NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

ARAGON PHARMACEUTICALS, INC., JANSSEN BIOTECH, INC., THE REGENTS OF THE UNIVERSITY OF CALIFORNIA, and SLOAN-KETTERING INSTITUTE FOR CANCER RESEARCH, Plaintiffs, v. EUGIA PHARMA SPECIALITIES LIMITED (A.K.A. EUGIA PHARMA SPECIALTIES LIMITED), AUROBINDO PHARMA USA, INC., and AUROMEDICS PHARMA LLC, Defendants.	**Honorable Stanley R. Chesler, U.S.D.J.** **Civil Action No. 2:22-cv-03186(SRC)** **OPINION & ORDER**
ARAGON PHARMACEUTICALS, INC., JANSSEN BIOTECH, INC., THE REGENTS OF THE UNIVERSITY OF CALIFORNIA, and SLOAN-KETTERING INSTITUTE FOR CANCER RESEARCH, Plaintiffs, v. HETERO LABS LIMITED UNIT V, and HETERO USA, INC., Defendants.	**Civil Action No. 2:22-cv-03212(SRC)**

CHESLER, U.S.D.J.

This matter comes before the Court on the application for claim construction by the parties in two coordinated cases.[1] In both cases, Plaintiffs are Aragon Pharmaceuticals, Inc. and Janssen Biotech, Inc. (collectively, "Plaintiffs.") In Civil Action No. 22-3186, Defendants are Eugia Pharma Specialties Limited (A.K.A. Eugia Pharma Specialties Limited), Aurobindo Pharma USA, Inc., and Auromedics Pharma LLC; in Civil Action No. 22-3212, Defendants are Hetero Labs Limited Unit V, and Hetero USA, Inc. (collectively, "Defendants.") These coordinated cases arise from Hatch-Waxman litigation regarding patents related to the drug Erleada®. Defendants are pharmaceutical companies which have filed ANDA applications to produce generic versions of this product. Plaintiffs own U.S. Patent No. 10,702,508 ("the '508 patent.") The parties seek claim construction of a term in the '508 patent.

ANALYSIS

I. The law of claim construction

A court's determination "of patent infringement requires a two-step process: first, the court determines the meaning of the disputed claim terms, then the accused device is compared to the claims as construed to determine infringement." Acumed LLC v. Stryker Corp., 483 F.3d 800, 804 (Fed. Cir. 2007). "[W]hen the district court reviews only evidence intrinsic to the patent (the patent claims and specifications, along with the patent's prosecution history), the judge's determination will amount solely to a determination of law." Teva Pharms. USA, Inc.

[1] Initially, the parties to a third coordinated case, Civil Action No. 22-2964, against Defendant Zydus, joined this claim construction proceeding. Shortly after opening briefs were filed, Plaintiffs withdrew claims of infringement of the '508 patent against Zydus, and so this claim construction has no impact on that case.

v. Sandoz, Inc., 135 S. Ct. 831, 841 (2015).

The focus of claim construction is the claim language itself:

> It is a bedrock principle of patent law that the claims of a patent define the invention to which the patentee is entitled the right to exclude. Attending this principle, a claim construction analysis must begin and remain centered on the claim language itself, for that is the language the patentee has chosen to 'particularly point[] out and distinctly claim[] the subject matter which the patentee regards as his invention.'

Innova/Pure Water, Inc. v. Safari Water Filtration Sys., 381 F.3d 1111, 1115-1116 (Fed. Cir. 2004) (citations omitted).

The Federal Circuit has established this framework for the construction of claim language:

> We have frequently stated that the words of a claim 'are generally given their ordinary and customary meaning.' We have made clear, moreover, that the ordinary and customary meaning of a claim term is the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention, i.e., as of the effective filing date of the patent application. The inquiry into how a person of ordinary skill in the art understands a claim term provides an objective baseline from which to begin claim interpretation. . .
>
> In some cases, the ordinary meaning of claim language as understood by a person of skill in the art may be readily apparent even to lay judges, and claim construction in such cases involves little more than the application of the widely accepted meaning of commonly understood words. In such circumstances, general purpose dictionaries may be helpful. In many cases that give rise to litigation, however, determining the ordinary and customary meaning of the claim requires examination of terms that have a particular meaning in a field of art. Because the meaning of a claim term as understood by persons of skill in the art is often not immediately apparent, and because patentees frequently use terms idiosyncratically, the court looks to those sources available to the public that show what a person of skill in the art would have understood disputed claim language to mean. Those sources include the words of the claims themselves, the remainder of the specification, the prosecution history, and extrinsic evidence concerning relevant scientific principles, the meaning of technical terms, and the state of the art.

Phillips v. AWH Corp., 415 F.3d 1303, 1312-1314 (Fed. Cir. 2005) (citations omitted).

II. Claim construction of the disputed term

The parties dispute the meaning of a phrase, "in combination with," that appears in claims 1 and 3 of the '508 patent:

> 1. A method of improving metastasis free survival in a male human with nonmetastatic castration-resistant prostate cancer, said method comprising administering to said male human an approved drug product comprising apalutamide in combination with androgen deprivation therapy.
>
> 3. A method of improving metastasis free survival in a male human with nonmetastatic castration-resistant prostate cancer, said method comprising providing to said male human an approved drug product comprising apalutamide in combination with androgen deprivation therapy, wherein the androgen deprivation therapy consists of orchiectomy or gonadotropin-releasing hormone agonists or antagonists.

Plaintiffs propose that, in both claims, the subject of "in combination with" is the method, which comprises 1) providing or administering an approved drug product which comprises apalutamide; and 2) androgen deprivation therapy. Thus, Plaintiffs contend, the method is the combination of administration of an approved drug product with androgen deprivation therapy. Defendants propose that, in both claims, the subject of "in combination with" is the approved drug product, which comprises 1) apalutamide; and 2) androgen deprivation therapy. Thus, Defendants contend, the approved drug product is the combination of apalutamide with androgen deprivation therapy.

The Court agrees with Plaintiffs. The Court acknowledges that a reader without skill in the relevant art could find the language at issue to be ambiguous, especially if that reader does not read the specification. The Federal Circuit recently restated some key principles of claim construction:

> We start with the claim language. *See Personalized Media Commc'ns, LLC v. Apple Inc.*, 952 F.3d 1336, 1340 (Fed. Cir. 2020) (explaining how we first, and primarily, rely on intrinsic evidence like claim language when construing claim terms). . . .
>
> In our view, the specification further supports this construction. *See Phillips v. AWH Corp*., 415 F.3d 1303, 1315 (Fed. Cir. 2005) (en banc) (characterizing the specification as highly relevant and "the single best guide to the meaning of a disputed term") (citation omitted).

Sequoia Tech., LLC v. Dell, Inc., 66 F.4th 1317, 1323 (Fed. Cir. 2023). This Court will apply the same approach to this claim construction dispute, beginning with an analysis of claim language, and then using the specification as a guide to the meaning of claim terms.

We begin by looking at the language of the claims. We see that both claims 1 and 3 could potentially be understood to express that the method is a combination of administration of a drug product and a deprivation therapy, or that the administered drug product is a combination of apalutamide and a deprivation therapy.

The next question is: did the applicants understand androgen deprivation therapy to be a drug product, or a treatment method? We look to the specification as a guide to understanding the claim language. The specification contains express definitions[2] of key terms:

> The term "androgen-deprivation therapy (ADT)" refers to the reduction of androgen levels in a prostate cancer patient to castrated levels of testosterone (<50 ng/dL). Such treatments can include orchiectomy or the use of gonadotropin-

[2] The Federal Circuit has held:

> "The specification acts as a dictionary when it expressly defines terms used in the claims or when it defines terms by implication." *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582, 39 U.S.P.Q.2D (BNA) 1573, 1577 (Fed. Cir. 1996). Where, as here, the patentee has clearly defined a claim term, that definition "usually . . . is dispositive; it is the single best guide to the meaning of a disputed term." *Id.*

Jack Guttman, Inc. v. Kopykake Enters., 302 F.3d 1352, 1360 (Fed. Cir. 2002).

> releasing hormone agonists or antagonists. ADT includes surgical castration (orchiectomy) and/or the administration of luteinizing hormone-releasing hormone ("LHRH") agonists to a human. Examples of LHRH agonists include goserelin acetate, histrelin acetate, leuprolide acetate, and triptorelin palmoate.
> . . .
> The term, "drug product" or "approved drug product" is product that contains an active pharmaceutical ingredient that has been approved for marketing for at least one indication by a governmental authority, e.g., the Food and Drug Administration or the similar authority in other countries.

'508 patent, col.10 ll.4-14; col.14 ll.16-21. The specification states that androgen deprivation therapy is a "treatment," and that orchiectomy is "surgical castration." According to the specification, androgen deprivation therapy is a treatment that can include a surgical procedure (orchiectomy) or administration of a hormone agonist to a human. We next inquire: can an approved drug product include a surgical procedure? The definition of "approved drug product" in the specification makes no mention of surgical procedures, referring only to an active pharmaceutical ingredient.[3]

Based upon the express definitions contained in the specification, orchiectomy is a surgical procedure and a treatment. The specification contains no evidence that the applicants understood orchiectomy to be an active pharmaceutical ingredient. The evidence contained in the specification supports Plaintiffs' proposed construction and is contrary to Defendants' proposed construction. The specification shows that the applicants understood androgen deprivation therapy to be a treatment method, not a drug product. The Court agrees with Plaintiffs that "in combination with" in claims 1 and 3 refers to a treatment method comprising administration of a drug product in combination with another treatment method which can

[3] This alone is dispositive of the claim construction issue before this Court. If Defendants' proposed construction were correct, the patent's express definition of "approved drug product" should permit inclusion of surgical castration within the drug product, but it does not.

include surgical castration or administration of LHRH agonists. Defendants have failed to persuade the Court that that "in combination with" in claims 1 and 3 refers to an approved drug product which is a combination of apalutamide and androgen deprivation therapy. The express definitions in the specification do not support the inference that the applicants understood androgen deprivation therapy to be an active pharmaceutical ingredient.

Defendants acknowledge the specification's definition of "approved drug product," but ignore the definition of "pharmaceutical combination." '508 patent, col.11 ll.42-57. In brief, the specification's definition of "pharmaceutical combination" states that it is "a product that results from the mixing or combining of more than one active ingredient." '508 patent, col.11 ll.43-44. The scope of the definition of "pharmaceutical combination" does not include a method which combines administration of an active ingredient with surgical castration.

Instead of looking to the patent's definition of "pharmaceutical combination," Defendants offer an assortment of extrinsic evidence, references to various FDA materials. Defendants have overlooked Federal Circuit law about the role of extrinsic evidence in claim construction: "while extrinsic evidence can shed useful light on the relevant art, we have explained that it is less significant than the intrinsic record in determining the legally operative meaning of claim language." Phillips, 415 at 1317. In Phillips, the Federal Circuit explained at length why this is so. Id. at 1317-19; see also Personalized Media Communs., LLC v. Apple Inc., 952 F.3d 1336, 1340 (Fed. Cir. 2020) ("When construing claim terms, we first look to, and primarily rely on, the intrinsic evidence, including the claims themselves, the specification, and the prosecution history of the patent, which is usually dispositive"); Ruckus Wireless, Inc. v. Innovative Wireless Sols., LLC, 824 F.3d 999, 1003 (Fed. Cir. 2016) ("Legal error arises when a court relies on

extrinsic evidence that contradicts the intrinsic record.")

The Court finds that the intrinsic evidence, discussed above, is dispositive: it suffices to resolve the parties' dispute over claim construction. Defendants have failed to persuade the Court that consideration of their extrinsic evidence is needed. As the Federal Circuit stated in Sequoia: "Our decision rests solely on the intrinsic evidence. We are unpersuaded by [the] arguments to the contrary, which rest on extrinsic evidence." Sequoia, 66 F.4th at 1324.

Lastly, Plaintiffs quote Renishaw PLC v. Marposs Societa' per Azioni, 158 F.3d 1243, 1250 (Fed. Cir. 1998): "The construction that stays true to the claim language and most naturally aligns with the patent's description of the invention [in the specification] will be, in the end, the correct construction." Defendants have cited nothing in the patent that describes the invention as a single drug product that combines an active ingredient with a surgical technique. Rather, what the inventors actually invented is a method of treating nonmetastatic castration-resistant prostate cancer, wherein the method combines administration of apalutamide with androgen deprivation therapy.

In conclusion, the Court construes the term at issue as follows. The Court agrees with Plaintiffs that "in combination with" in claims 1 and 3 refers to a treatment method comprising a combination of: 1) administration of a drug product comprising apalutamide; and 2) another treatment method which can include surgical castration or administration of LHRH agonists.

SO ORDERED.

s/ Stanley R. Chesler
STANLEY R. CHESLER, U.S.D.J.

Dated: August 9, 2023